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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,869	05/08/2002	James Michael Rini	12243.23USWO	8589

23552 7590 12/13/2004

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,869

Applicant(s)

RINI ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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DETAILED ACTION

Claims 1-35 are presented for examination.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, drawn to a secondary or three-dimensional structure of a purified glycosyltransferase associated with a moiety which may be a nucleotide sugar donor, acceptor, or metal cofactor, classified in class 435, subclass 193.
- II. Claims 11-13, drawn to a crystalline form of a glycosyltransferase, classified in class 435, subclass 193.
- III. Claims 14-17, drawn to a secondary or three-dimensional structure of a binding site of a glycosyltransferase, classified in class 530, subclass 300.
- IV. Claims 18 and 19, drawn to a secondary or three-dimensional structure of an spsA GnT 1 core domain of a glycosyltransferase, classified in class 530, subclass 300.

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- V. Claims 20, 27, 29 and 30, drawn to a modulator of glycosyltransferase activity, classified in class 536, subclass 4.1.
- VI. Claim 21, drawn to a method determining the three-dimensional structure of a polypeptide, classified in class 436, subclass 86
- VII. Claims 22 and 24-26, drawn to methods of identifying potential modulators of a glycosyltransferase, classified in class 435, subclass 15.
- VIII. Claim 23, drawn to a method of identifying modulators of a glycosyltransferase, classified in class 435, subclass 15.
- IX. Claim 28, drawn to a method for designing glycosyltransferase inhibitors, classified in class 703, subclass 1.
- X. Claim 31, drawn to a method for treating disease, classified in class 514, numerous subclasses, including subclass 23.
- XI. Claims 32 and 33, drawn to a method of preparing a medicament, classified in class 702, subclass 22.
- XII. Claims 34 and 35, drawn to machine readable media, classified in class 702, subclass 19.

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The inventions are distinct, each from the other because of the following reasons:

Inventions I through V and XII are patentably distinct products. Each of the claimed products has a different structure than the other products and has structural elements which are not present in any of the other products. By virtue of their different structural elements, the various products are capable of supporting different patents. Moreover, because each of the products has a different structure, a reference which anticipates one product would not necessarily anticipate or render obvious any of the other products, thus demonstrating a significant burden on the search and examination process. Moreover, invention XII, direction to machine readable media is clearly unrelated to the other inventions since machine readable media clearly has a different mode of operation, different function, and different effect than the enzymes, enzyme compositions, peptides and therapeutic agents recited in the remainder of the claims (MPEP § 806.04, MPEP § 808.01). Thus, restriction between the various product inventions is clearly proper under 35 U.S.C. 121.

Similarly, inventions VI through XI are patentably distinct processes. Each of the claimed processes recites different processes steps than the other process. By virtue of their

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different processes steps, the various processes are capable of supporting different patents. Moreover, because each of the processes has different steps, a reference which anticipates one process would not necessarily anticipate or render obvious any of the other processes, thus demonstrating a significant burden on the search and examination process. Thus, restriction between the various product inventions is clearly proper under 35 U.S.C. 121.

Inventions I through IV are related to inventions VI through IX as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products as claimed can be used in materially different processes, such as assays for determining glycosyltransferase enzymatic activity by actually measuring catalytic reaction rates *in vitro*.

Inventions X and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2)

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that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product, a medicament, can be made by synthetic and testing methods which do not involve the determination of the crystalline structure of an enzyme.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, and because the search required for any one Group is not required for any other, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must

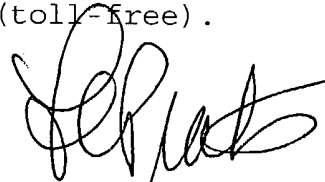
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be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C Prats
Primary Examiner
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FCP